

OLTAD FILM-COATED TABLETS

Tadalafil 20mg

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What Oltad is used for

Oltad contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Oltad is used to treat adult men with erectile dysfunction. This is when a man cannot get, or keep a hard erect penis suitable for sexual activity

How Oltad works

Erectile dysfunction

Following sexual stimulation Oltad works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. It is important to note that Oltad does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

Before you use Oltad

- When you must not use it

Do not take Oltad:

- If you are allergic to tadalafil or any of the other ingredients in this medicine (see section 8. *Product description*).
- If you are taking any form of nitrates such as amyl nitrite. This is a group of medicines used in the treatment of angina pectoris (chest pain). Oltad has been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure, tell your doctor.
- If you have serious heart disease or recently had a heart attack within the last 3 months.
- If you recently had a stroke within the last 6 months
- If you have low blood pressure or uncontrolled high blood pressure.
- If you ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy

(NAION), a condition described as "stroke of the eye"

- If you are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e. high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e. high blood pressure in the lungs secondary to blood clots.) PDE 5 inhibitors such as Oltad, has been shown to increase the hypertensive effects of this medicine. If you are taking riociguat or are unsure, please tell your doctor.

- Before you start to use it

Talk to your doctor before taking Oltad. Be aware that sexual activity carries a possible risk to patients with heart disease because it puts extra stress on your heart. If you have a heart problem, you should tell your doctor.

Before taking the tablets, tell your doctor if you have:

- Sick cell anemia (an abnormality of red blood cells)
- Multiple myeloma (cancer of the bone marrow)
- Leukaemia (cancer of the blood cells)
- Any deformation of your penis
- A serious liver problem
- A severe kidney problem
- Any heart problems
- Problems with your blood pressure
- Any hereditary eye disease

Oltad is not intended for use by women.

Children and adolescents

Oltad is not intended for use by children and adolescents under the age of 18.

- Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Do not take Oltad if you are already taking nitrates.

Some medicines may be affected by Oltad or they may affect how well Oltad will work. Tell your doctor or pharmacist if you are already taking:

- Nitrates (for chest pain)
- An alpha blocker (used to treat high blood pressure or urinary symptoms associated with benign prostatic hyperplasia)
- Other medicines to treat high blood pressure (eg. doxazosin)

- A 5-alpha reductase inhibitor (used to treat benign prostatic hyperplasia)
- Protease inhibitors for treatment of AIDS or HIV infection (ritonavir)
- Phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines)
- Rifampicin, erythromycin, clarithromycin (to treat bacterial infections)
- Medicines such as ketoconazole tablets or itraconazole (to treat fungal infections)
- Other treatments for erectile dysfunction (PDE5 inhibitors)
- Theophylline (medicine to treat respiratory disease)
- Ethinylestradiol (an oral contraceptive pill)
- Terbutaline (medicine for asthma)
- Riociguat (medicine for treating high blood pressure at arteries of lungs)

How to use Oltad

- How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended starting dose is 10mg or 20mg taken before sexual activity. Your doctor will check the suitable dose for you.

- When to use it

Oltad tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food. You may take Oltad tablets at least 30 minutes before sexual activity. Oltad may still be effective up to 36 hours after taking the tablet.

- How long to use it

Do not take Oltad more than once a day

- If you forget to use it

Oltad is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use

- If you use too much (overdose)

If you or anyone else takes more tablets than they should, tell your doctor or go to a hospital immediately, taking the medicine or pack with you. You may experience side effects described in section 4.

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While you are using it

- Things you must do

- Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- If you experience sudden decrease or loss of vision, stop taking Oltad and contact your doctor immediately.
- Decreased or sudden hearing loss has been noticed in some patient taking Tadalafil. Although it is not known if the event is directly related to tadalafil, if you experience decreased or sudden hearing loss, stop taking Oltad and contact your doctor immediately.

- Things you must not do

This medicine has been prescribed for you only. Do not pass it on to others or shared with others. It may harm them even if they have signs of illness are the same as yours.

- Things to be careful of

- Some men taking Oltad in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.
- Oltad might affect sperm concentration, consult your doctor before using it.
- This product contains lactose. If you have an intolerance to some sugars, contact your doctor before taking this medicine.
- Drinking alcohol may affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take Oltad, avoid excessive drinking (blood alcohol level of 0.08% or greater) since this may increase the risk of dizziness when standing up.
- Grapefruit juice may affect how well Oltad will work and should be taken with caution. Talk to your doctor for further information.

Side effects

Like all medicines this medicine can cause side effects although not everybody gets them. These effects are normally mild to moderate in nature.

If you experience any of the following side effects stop using the medicine and seek medical help immediately:

- Allergic reactions including rashes (frequency uncommon)
- Chest pain – do not use nitrates but seek immediate medical assistance (frequency uncommon)
- Prolonged and possibly painful erection after taking tadalafil (frequency rare). If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- Sudden loss of vision (frequency rare)

Other side effects have been reported and these are listed below, separated by indication:

Side effects in erectile dysfunction

Common

- Headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion, indigestion and reflux.

Uncommon

- Dizziness, stomach ache, feeling sick, being sick (vomiting), reflux, blurred vision, eye pain, difficulty in breathing, presence of blood in urine, prolonged erection, pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure, nose bleeds, ringing in the ears, swelling of the hands, feet or ankles and feeling tired

Rare

- Fainting, seizures and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing, hives (itchy red welts on the surface of the skin), penile bleeding, presence of blood in semen and increased sweating.

Heart attack and stroke have also been reported rarely in men taking tadalafil. Most of these men had known heart problems before taking this medicine.

Partial, temporary or permanent decreased or loss of vision in one or both eyes has been rarely reported.

Some additional rare side effects have been reported in men taking tadalafil that were not seen in clinical trials. These include:

- Migraine, swelling of the face, serious allergic reaction which causes swelling of the face or throat, serious skin rashes, some disorders affecting blood flow to the eyes, irregular heartbeats, angina and sudden cardiac death. The side effect dizziness has been reported more frequently in men over 75 years of age taking Oltad. Diarrhoea have been reported more frequently in men over 65 years of age taking Oltad.

If you get any side effects, talk to your doctor or pharmacist. This includes possible side effects not mentioned in this leaflet.

You may report any side effects or adverse reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) of Vaccines (AEFI)]

Storage and Disposal of Oltad

Storage

- Keep this medicine out of sight and reach of children.
- Store below 30°C in the original package.

Disposal

- Do not use this medicine after the expiry date stated on the carton and blister after “EXP”.
- The expiry date refers to the last day of that month
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description

- What it looks like

Oltad 20mg tablets are yellow, round, convex film coated tablets, plain on both sides, with diameter of nucleus 10.3mm. The tablets are packed in PVC/PE/PVDC-Alu blisters in carton boxes of 4 and 8 tablets.

- Ingredients

- Active ingredient

The active substance is tadalafil. Each tablet contains 20mg tadalafil.

- Inactive ingredients

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Tablet core: lactose monohydrate, hydroxypropylcellulose, croscarmellose sodium, sodium laurilsulphate, microcrystalline cellulose, magnesium stearate.

Film coating: hypromellose, lactose monohydrate, triacetin, titanium dioxide (E171), talc, iron oxide yellow (E172).

- MAL number
MAL21016013AZ

Manufacturer

Medochemie Ltd (Far East) Ltd, (Oral Facility), No. 40 Street 6 Vietnam Singapore Industrial Park II, Binh Duong Industry Service Urban Comple, Hoa Phu ward, Thu Dau Mot city, Vietnam

Product registration holder

Komedic Sdn Bhd, 4 Jalan PJS 11/14, Bandar Sunway, 46150 Petaling Jaya, Selangor D.E.

Date of revision

14/11/2024

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NPRA(R2)19/215.